

### **REMARKS/ARGUMENTS**

Claims 1-21 are pending in the instant application. The following remarks are believed to be fully responsive to the Office Action.

#### **35 USC § 103(a) Rejection**

Claims 1-21 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,948,940 to Malthe-Sorensen et al. ("Malthe-Sorensen").

It is important to point out that the Examiner holds that Malthe-Sorensen describes using 2-methoxy-ethanol as solvent in the production of iohexol. The Examiner further holds that it is routine for a skilled artisan to use art recognizing alternative solvents, and that it would have been obvious to a person skilled in the art to use 1-methoxy-2-propanol in Malthe-Sorensen. Applicants respectfully disagree.

Malthe-Sorensen describes a process for the production of iohexol, wherein said process comprises reacting 5-(acetamido)-N,N'bis(2,3-dihydroxypropyl)-2,4,6-triiodoisophthalamide with a 2,3-dihydroxypropylating agent in the presence of 2-methoxy-ethanol. Malthe-Sorensen also teaches the purification of iohexol using a solvent mixture comprising 2-methoxy-ethanol. In addition it was known from WO02/083623, as discussed in the present application, page 2, lines 1-2, to use 1-methoxy-2-propanol as solvent in the purification by recrystallization of iohexol. No prior art document suggests using 1-

methoxy-2-propanol as solvent in the alkylation step.

Knowing that 1-methoxy-2-propanol is used as the solvent in the purification by recrystallization of iohexol, one skilled in the art would not expect that a solvent mixture that is dominated by the same solvent would also be used in the alkylation step. The reason for this is that in the alkylation step it is required that the solvent shows good solubility for 5-(acetamido)-N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodoisophthalamide and that the product (iohexol) does not precipitate during the reaction, whereas in the purification step the solvent used should show little solubility for the product (iohexol). A person skilled in the art would therefore not expect that 1-methoxy-2-propanol could be used as the dominant solvent in both the alkylation and the purification step, and would not think or suggest using 1-methoxy-2-propanol as an alternative to 2-methoxy-ethanol in the production described by Malthe-Sorensen. Malthe-Sorensen does describe using 2-methoxy-ethanol as a solvent in both the alkylation step and in the purification step, however, 2-methoxy-ethanol is not the dominant solvent in the solvent mixture used in the purification step. The solvent mixture only comprises a small amount of 2-methoxy-ethanol, see claim 1.

Applicants wish to point out here that it is well settled in case law that prior patents such as Malthe-Sorensen are references only for what they clearly disclose or suggest. It is not proper use of a patent as a reference to modify its structure to one which prior art references do not suggest. *In re Randol and Redford*, 425 F.2d 1268, 165 U.S.P.Q. 586, 588 (C.C.P.A. 1970). A reference must be considered not just for what it expressly teaches, but also for what it fairly suggests to one who is unaware of the claimed invention. *In re Baird*,

16 F.3d 380, (Fed. Cir. 1994). Additionally, Applicants respectfully submit that it is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986). (emphasis added).

Hence, it is not obvious to one skilled in the art that 1-methoxy-2-propanol known to be used as the dominant solvent in the purification step also could be used as the dominant solvent in the alkylation step. By comparing the examples 1 to 3 in the present application with example 1 in Malthe-Sorensen, one can see that in the present invention's reaction mixture is formed after the alkylation step using 1-methoxy-2-propanol gives a higher content of iohexol than is the case in Malthe-Sorensen. Example 3 in the present application also shows that the use of 1-methoxy-2-propanol in both the alkylation and purification steps give a lower content of undesired by-products in the final product compared to example 2 in Malthe-Sorensen.

Accordingly, Applicants respectfully request that the Examiner withdrawal the rejections for claims 1-21 under 35 U.S.C. §103(a) and direct that claims 1-21 be allowed.

**CONCLUSION**

Upon entry of this Amendment, claims 1-21 remain pending. Applicants submit that all outstanding issues have been addressed, and that claims 1-21 are in condition for allowance, which action is earnestly solicited.

Again, the Commissioner is hereby authorized to charge any fees under 37 CFR §1.16(j) or 37 CFR 1.136(a) which may be required, or credit any overpayment, to Deposit Account No. 502-665 in the name of GE Healthcare, Inc.

Should any other matters require attention prior to allowance of the application, it is requested that the Examiner contact the undersigned.

Respectfully submitted,

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